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III. Packaging and Container Regulations

IV. Food Additive Regulations

V. Pesticides and Other Contaminants

VII. Other Specific Standards

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Note: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service at the U.S. Embassy/Tokyo for exporters of U.S. agricultural products. While great care was taken in preparation of this report, information provided may not be completely accurate due to either changes in policies since its preparation, or because clear and consistent information about these policies was not available at the time of publication. It is highly recommended that U.S. exporters verify the relevant import requirements with their foreign customers, who normally have the most updated information on local requirements and can research such matters with local authorities, prior to exportation. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Adobe's Japanese language module may need to be installed to view pdf documents from the Japanese government and organizations even if they are in English.

FOOD LAWS

There are three major laws pertaining to food safety and standards; the Food Safety Basic Law, the Food Sanitation Law and the Japan Agricultural Standards Law. The Food Safety Basic Law sets the principles for developing a food safety regime and also sets up the role of the Food Safety Commission, a food related risk assessment body (for details, please see JA3029). The Food Sanitation Law ensures the safety and sanitation of foods through the Ministry of Health, Labor and Welfare (MHLW), a food risk management agency. The law prohibits the sale of foods containing harmful substances. It also prescribes the standards for foods, additives, food containers and packages, and certain toys. The law is available in English on the following Japan External Trade Organization (JETRO) website: http://www.jetro.go.jp/en/market/regulations/.

The general requirements and standards are set by MHLW and apply to all types of foods including imported foods. Imported foods that do not meet these requirements will not be allowed entry. These requirements and standards place the primary emphasis on ingredient and manufacturing standards. It is strongly recommended that in the event a product label does not clearly indicate additives, preservatives, coloring, spices or flavorings, that a certificate with detailed descriptions of the ingredients (names of the chemical compounds, chemical names and international index numbers of the colors, etc.) be attached to each shipment in order to expedite import procedures. Details of food importing procedure may be viewed on the MHLW website at: http://www.mhlw.go.jp/english/topics/importedfoods/1.html.

Before shipping a new or unknown product to Japan, MHLW suggests that the Japanese importer deliver a small sample of the product to be imported to the MHLW port inspectors' office with a certificate guaranteeing compliance with required product regulations. These samples should be inspected to ensure that no importation problems exist before the actual product is commercially exported to Japan. It is strongly recommended that products not be shipped until product compliance has been verified. Another option is to have a sample of the product tested by one of the MHLW official or registered laboratories located in the United States. A full list of the registered laboratories is found on the following MHLW website: http://www.mhlw.go.jp/topics/yunyu/5/dl/a3.pdf.

The Ministry of Agriculture, Forestry and Fisheries (MAFF) is also involved in food safety risk management, mainly in the area of food labeling through the Japan Agricultural Standards (JAS) Law, and animal and plant health protection through a series of guarantine laws. MAFF is also responsible for organic food standards through the JAS Law. The JAS laws and outlines of animal and plant quarantine regulations can be viewed by choosing the link to "Guide to the JAS System for Agricultural and Forest Products" on the following JETRO website: http://www.jetro.go.jp/en/market/regulations/index.html. Those on organic foods and other quality-based food labeling regulations are located on the following MAFF website: http://www.maff.go.jp/soshiki/syokuhin/hinshitu/e_label/index.htm Information on the Japanese organic standards with background on the export agreements with Japan is available at the website of the Agricultural Marketing Service (AMS), USDA at: http://www.ams.usda.gov/nop/NOP/TradeIssues/Japan.html

II. LABELING REQUIREMENTS

Labeling Required by the Ministry of Health, Labor and Welfare

MHLW requires that the label for imported food products should include the following information, in Japanese:

- Name of the product;
- Country of origin;
- Name of the importer;
- Ingredients, other than additives, in descending order of weight percentage;
- Food additives in descending order of weight on a separate line from other ingredients;
- The net weight in metric units only. A system of average net weight tolerances of packages or certain commodities is set by MHLW;
- "Best-before date" or "Expiry of consumption" on products whose quality changes rapidly;
- Method of use, storage instructions, or preparation, when established by MHLW for the product or when its absence could cause confusion;
- Labeling of certain biotechnology ingredients (limited to foods made from corn, soybeans rapeseed, and cottonseeds, listed on table 5-3 on the following website) where the genetically modified content of the labeled ingredient exceeds 5 percent. See GAIN report JA7040 and the MHLW website (http://www.mhlw.go.jp/english/topics/qa/gm-food/index.html) for more details. Another good source of detailed information on labeling of biotech foods is:
 - http://www.maff.go.jp/soshiki/syokuhin/hinshitu/e_label/index.htm (Please note that the United States is no longer commercially producing biotech potatoes. Therefore, IP handling is not required for non-biotech U.S. potatoes until the point where the adventitious presence of biotech potato can be suspected, e.g. until the arrival at Japanese ports.
- As of July 2005, exporters who follow the MAFF biotechnology-labeling scheme described later in this report will also be considered to have met the MHLW labeling regulations;
- Allergen labeling; required by MHLW on foods containing any of the five ingredients known to cause significant allergic reactions; wheat, buckwheat, egg, milk and peanuts. MHLW also recommends that any possible additional allergens be listed on the label when present in the food: abalone, squid, salmon roe, prawn, orange, crab, kiwi fruit, beef, treenuts, salmon, mackerel, soybean, chicken, pork, mushrooms, peach, yam, apple, banana, and gelatin. For details, please see GAIN report JA5037 and the MHLW website (http://www.mhlw.go.jp/english/topics/ga/allergies/index.html).

The minimum font size required for labels is 8-point for all characters. It is recommended that the importer double-check the labels to ensure conformity.

Pharmaceutical Products and Supplements

Pharmaceutical products and supplements must comply with the Pharmaceutical Affairs Law or the Cosmetic Law for entry into Japan. To comply, the importers must submit an application for approval to import to MHLW, with certain required data through the Tokyo Metropolitan Government Office or local prefecture government office, depending on the location of the importer. The local government office, or MHLW if necessary, reviews the pharmaceutical products for approval based on the application, which must include effectiveness data, on a case-by-case basis.

Normally, it takes one year or more to have an import permit granted, depending on the product. In addition, a company without a license to handle pharmaceutical products and/or cosmetics cannot market this class of product. Therefore, interested companies should request more detailed information on the application procedures from MHLW through the importer.

Nutritional Labeling

While nutritional labeling is voluntary in Japan, MHLW requires food manufacturers that provide nutritional information on a label to follow MHLW nutritional labeling guidelines. Nutritional labeling must be in Japanese, thus the U.S. nutritional fact panel is not acceptable. If a company includes information about even one part of the nutrition information (e.g., vitamin content), then all five major nutritional facts about the food must be included. These 5 items are 1) calories (kilo calories) 2) protein (grams) 3) fat (grams), 4) sugar or carbohydrate (gram) 5) sodium (milligrams or grams in cases above 1,000 mg) plus 6) other components to be labeled, in this order. The content of each component is to be shown using the unit in the parenthesis per unit of food (e.g., 100 g, 100 ml, 1 serving, 1 package, etc.). The label must use a font size of at least 8-point, except for the cases in which the labeling area is less than 100 cm².

In addition, MHLW regulates certain health-related claims and components. For dietary fiber, protein, calcium, iron, Vitamin A, Vitamin B1, Vitamin B2, niacin, Vitamin C and Vitamin D, health-related claims such as "rich in" or "containing" must meet MHLW's minimum content level standards. In order for claims such as "less" or "no" nutritional components such as calories, fat, saturated fatty acid, sugar and sodium, the content of the components must be lower than MHLW's maximum content level standards. For example, when a "no sodium" or "low or less sodium" claim is made, the sodium content must be lower than 5 mg and 120 mg per 100 g of food, respectively and when a "no fat" or "low or less fat" claim is made, the fat content must be lower than 0.5 g and 3 g per 100g of food, respectively.

Foods for specified health uses (FOSHU) are those to which a "functional" ingredient has been added for a specific health effect. To indicate a specific health effect (e.g., "reduces cholesterol") MHLW must review and approve the health claim under the Nutrition Improvement Law. Foods approved by MHLW are foods which have been designated to maintain and promote good health, including foods that improve gastro-intestinal conditions, foods for those with high cholesterol, foods for those with high blood pressure, foods related to mineral absorption, non-carcinogenic foods, and foods for those concerned about their blood sugar level.

Overseas applicants for FOSHU may consult with the Office of Newly Developed Foods, Department of Food Safety, MHLW, and submit an application. The National Nutrition Institute then tests the product on its claims and a nutrition expert committee of MHLW reviews the results. Once the approval is granted, MHLW notifies the overseas applicant.

Labeling Required by Ministry of Agriculture, Forestry and Fisheries (MAFF)

Separate from labeling requirements under the MHLW Food Sanitation Law, MAFF requires manufacturers to label their products in accordance with quality labeling standards established under the Standardized Quality Labeling System of the Japan Agricultural Standards (JAS) Law (see "Labeling and Standards" under "Policy Information" on the following MAFF website: http://www.maff.go.jp/eindex.html

The current JAS Law requires labeling of:

- (1) Place of origin for all perishable foods (produce, meat, seafood, dairy), see "Labeling Fresh Foods" under "Labeling" on the following MAFF website: http://www.maff.go.jp/soshiki/syokuhin/hinshitu/e_label/index.htm
- (2) Ingredients derived from biotechnology- limited to foods made from corn, soybeans and potatoes where the genetically modified content of the labeled ingredient exceeds 5 percent (see GAIN report <u>JA6049</u> and "Genetically modified foods" under "Labeling" on the MAFF website (http://www.maff.go.jp/soshiki/syokuhin/hinshitu/e_label/index.htm) for more information).
- (3) Organic labeling, including mandatory third party certification for products labeled as "organic." For more information, please refer to "Organic" under "Specific JAS" on the following MAFF website:

 http://www.maff.go.jp/soshiki/syokuhin/hinshitu/e_label/index.htm

The following items are required on labels for processed foods under the JAS Law: (1) name of product (2) ingredients (3) net amount of contents (4) best-before date (5) name of manufacturer (importer for imported foods) (6) method of preservation. Note there are many processed foods, which have additional Individual Quality Labeling Standards. For details see "Processed foods" under "Labeling" on the following MAFF website: http://www.maff.go.jp/soshiki/syokuhin/hinshitu/e_label/index.htm

III. PACKAGING AND CONTAINER REGULATIONS

In accordance with Article 16 of the MHLW Food Sanitation Law, no person shall sell, manufacture, or import with the intent to sell or use in business any apparatus, container, or package which contains or bears toxic or injurious substances and may injure human health, or any apparatus, container, or package which may injure human health by having harmful influence on foods and additives through contact therewith.

To prevent the use of harmful containers or packaging material, MHLW may establish standards for methods of manufacturing them. MHLW has established specifications for synthetic resins, metal cans, and containers/packages made of glass, ceramic, enamel, or rubber. For further details, please refer to the following JETRO website: http://www.jetro.go.jp/en/market/regulations/ (see "Specifications and Standards for Foods, Food Additives, etc., Under The Food Sanitation Law") and the following FFCR website: http://www.ffcr.or.jp/zaidan/ffcrhome.nsf/TrueMainE?OpenFrameSet.

In April 2000, Japan implemented a new Package Recycling Law that requires paper and plastic packaging to be appropriately labeled and recycled. Private industry is being required to pay all costs associated with this recycling. For imported products, part of the recycling cost will be borne by importers. However, it is possible that Japanese importers will take recycling costs into account when choosing the goods they import, and some Japanese importers may ask their suppliers overseas to cooperate in supplying the additional labeling.

The new labeling law became fully mandatory on April 1, 2003. Importers are responsible for making sure that there are appropriate labels on all packaging and containers used for imported goods. More details may be found on the Ministry of Economy, Trade and Industry's website (http://www.meti.go.jp/english/information/data/cReEffect01e.html) and in GAIN reports JA9121 and JA9022.

IV. FOOD ADDITIVE REGULATIONS

MHLW requires a safety assessment for food additives. Additives, both artificial and natural, that do not appear on MHLW's positive list of approved additives cannot be used in a food product. While CODEX standards are considered in MHLW's safety assessment, only additives that have been approved by MHLW may be used in foods and beverages sold in Japan.

Restrictions on the use of a food additive are based on regulations limiting the amounts of the additive used in the final food preparation. Many food additives which are commonly used in the United States, such as some food coloring and preservatives, cannot be used in Japan, and foods containing even traces of such additives cannot be imported. In addition to Japan's review of the general assessment of an additive's safety, MHLW approves the additive for use on a specific product.

The Japanese approved food additive list shows the additives that are approved for use in food products, the purpose that the additive must be used for (preservative, antioxidant, etc.), the foods that the additives are allowed to be used in, and the maximum tolerances allowed in the food. For a full list of approved additives, approved uses, and tolerances, please refer to MHLW's "Food Additive" website

http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/index.html_and the following FFCR website: http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/eng.h-page

To help expedite customs clearance, the following information should be provided at the time of import:

- The chemical names and content in parts per million (ppm) of all synthetic additives having tolerance levels set by MHLW.
- Names of all natural food additives.
- Artificial colors identified by their chemical name and international color index number.
 Natural color descriptions must also be provided to determine acceptability for the specific product exported.
- Artificial flavors identified by their chemical name as they appear on the Japanese approved additive list for the specific product exported.

Food Additive Approval Process

MHLW will review applications for the approval of new food additives and the approval of new uses and tolerances for additives already approved. MHLW decides on the approval of food additives in part based on the concept of the average daily intake of the substance. Thus, MHLW looks at all of the products in which a certain additive is used prior to granting approval. For example, a preservative approved at a certain level for margarine may not be approved as a preservative for pickles. For this particular additive to be approved for pickles, an applicant must supply MHLW with the relevant technical data to demonstrate that the additional use would not result in unacceptable daily intake levels. The application procedure for the approval of new food additives or new uses of approved additives is described in "Guidelines for Designation of Food Additives and for Revision of Standards for Use of Food Additives", which can be obtained from the FAS office in the U.S. Embassy, Tokyo

(<u>agtokyo@usda.gov</u>) upon request or online from Appendix 5 on the following FFCR website: <u>http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/PDF/\$FILE/Guideline.pdf</u>

V. PESTICIDES AND OTHER CONTANIMENTS

On May 29, 2006 Japan implemented new regulations on residues of agricultural chemicals, feed additives and veterinary drugs (hereinafter referred to as agricultural chemicals) in food. To implement the new regulation, MHLW announced the provisional MRLs for 758 agricultural chemicals on November 29, 2005, in addition to around 10,000 existing official MRLs. Those new provisional MRLs will remain "provisional" until they are reviewed, which will take place over the next several years. After a risk assessment of a provisional MRL is completed, an official MRL can be established. Together the existing MRLs and the provisional MRLs make up the "positive list". After the implementation date of May 29th, 2006, foods containing residues exceeding the MRL levels on the positive list are regarded as violations of the Food Sanitation Law and are rejected at the port. After two violations of a particular MRL the entire U.S. industry for that product could be subject to very strict sanctions, which usually includes costly testing and lengthy delays at the port. MHLW established a uniform limit of 0.01 ppm, which is the maximum allowable limit for combinations of chemicals and commodities that have no official or provisional MRLs. MHLW also listed 15 chemicals for which no residues may be detected because of high human health risks, and 65 substances used as agricultural chemicals for exemption from the regulation. MHLW established provisional MRLs on some processed foods in addition to raw commodities but for residues in processed foods without MRLs, MHLW will use the MRLs of the raw ingredients after taking into consideration things like concentration ratios.

Other information about the positive list system, including the actual MRLs, can be found on MHLW's webpage in English at:

http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/index.html

Additional information can also be found in GAIN reports JA6004, JA6011, JA6025, JA6027, and JA6030.

Monitoring of Chemical Residues

Quarantine offices (for imported crops) and local government laboratories (for both imported and domestically produced crops) conduct monitoring tests for pesticides and veterinary drugs. The purpose of the monitoring tests is to check whether crops and livestock products in the marketplace comply with established MRLs and other food safety regulations. Any product found to contain a substance in violation of the MRL regulations will not be allowed to be sold in Japan.

Since 1985, MHLW has conducted surveys of residues, including pesticides and veterinary drugs without MRLs, to obtain basic data for the establishment of MRLs. The monitoring test results typically show that less than 0.1% of the samples tested were above the established MRLs. Crops not meeting the standards and specifications of the Food Sanitation Law, including MRLs, were discarded, re-exported, reconditioned, or otherwise discarded. Each year MHLW decides on a specific monitoring plan. Details of the FY2007 monitoring plan can be found at the following websites: http://www.mhlw.go.jp/topics/yunyu/dl/tp0130-1z.pdf.

Please note that enhanced inspection plans after a violation will be issued separately.

Results of FY2006 inspection results can be found at the following websites; http://www.mhlw.go.jp/english/topics/importedfoods/dl/6-6.pdf

Establishment of MRLs for Pesticides

To establish MRLs for pesticides used in Japan or in foreign countries, an application must be submitted. Data needed for evaluation usually includes data on acute toxicity, subacute toxicity, chronic toxicity, carcinogenicity, reproductive toxicity, teratogenicity, mutagenicity, pharmacokinetic and general pharmacological parameters, animal metabolism, and plant metabolism as well as residue data (for commodities treated with target pesticides). Details of the procedure for application for establishment and revision of MRLs used outside Japan are available at the following MHLW website:

http://www.mhlw.go.jp/english/topics/foodsafety/residue/index.html

Other Contaminants

Some foods have naturally occurring substances which may be considered harmful to the human body or which may be contaminated with harmful substances or germs during their manufacturing. Because of this, inspection officials look for the following items:

- 1. Aflatoxin levels in peanuts, peanut products including peanut butter, nuts, spices, and some grain products;
- 2. Poisonous fish:
- 3. Shellfish poisons (diarrhea poison and paralytic poison of bivalves);
- 4. Cyanogen (butter beans, white beans, saltani beans, etc.);
- 5. Methanol in distilled liquors and wines;
- 6. Gossypol in cottonseeds other than for oil extraction;
- 7. Salmonella in meat meant to be consumed raw;
- 8. Listeria in some natural cheeses;
- 9. Trichina in game birds, etc;
- 10. Radioactive substances usually in foods of European origin;
- 11. Decomposed or deteriorated foods of all kinds.

VI. OTHER REGULATIONS AND REQUIREMENTS

Food import procedure under the Food Sanitation Law is described on the following MHLW website: http://www.mhlw.go.jp/english/topics/importedfoods/1.html

Required Importation Documents:

Import documents required for entry into Japan are as follows:

- 1. Import Notification Two copies
- 2. Health Certificate
- 3. Results of Examination
- 4. Documents showing the ingredients, additives and manufacturing process (Manufacturer Certification)

Cargo found in violation of the Food Sanitation Law is re-exported, destroyed, or otherwise discarded. In addition, the following must also be presented upon importation where appropriate:

Other Documents - Processed foods imported for the first time must contain additional documents with more detailed information than that stated on the import notification, including information about raw materials, ingredients, and the manufacturing process.

Bovine free certification – Due to BSE, processed foods that could possibly contain ingredients from ruminants, such as gelatin, must certify that the ingredients are not derived from ruminants in the United States. Dairy products are exempted from this requirement. Details are described in a GAIN report JA4017.

U.S. Laboratories Certified by the Government of Japan

MHLW has certified certain U.S. laboratories to test foods and beverages for compliance with Japan's Food Sanitation law for export to Japan. U.S. products will not need to be tested upon arrival to Japan if an analytical certificate from a laboratory approved by MHLW accompanies the shipment. As long as the certificate issued by the U.S. laboratory is complete and satisfactory, no additional tests for the products will be required by MHLW when the product is inspected at the port of entry. A full list of MHLW approved U.S. laboratories is available on the following MHLW website: http://www.mhlw.go.jp/topics/yunyu/5/dl/a3.pdf

VII. OTHER SPECIFIC STANDARDS

Biotechnology Foods

The Government of Japan requires an environmental and food safety assessment of biotechnology products prior to their importation into Japan. No foods or beverages or their ingredients may contain materials produced through recombinant DNA techniques that have not been approved by the Government of Japan. As of July 2007, Japan has approved 77 biotech events for food, 50 for feed, 55 for planting and 14 for food additives

MHLW coordinates the Government of Japan's food safety assessment of biotechnology plants. Upon receipt of applications prepared in accordance with the guideline requirements, MHLW asks the Food Safety Commission's expert committee to conduct a risk assessment examining the biological characteristics and potential impact on public health. MHLW and the Food Safety Commission maintain a science-based approval process, and 77 varieties of genetically modified plants have been approved as of July 2007, including soybeans, canola, corn, potatoes, sugar beet and cotton.

MHLW monitors imports for unapproved varieties of biotechnology products in order to enforce its zero tolerance for varieties whose safety has not been confirmed. Any shipment found to contain an unapproved variety may not be imported into Japan.

MAFF also conducts mandatory environmental safety assessments as required by the Biosafety Protocol. MAFF perform feed safety assessments (where appropriate) for biotechnology products. MAFF has confirmed the environmental safety of 55 plants produced through biotechnology; including soybeans, corn, rapeseed, cotton, tomatoes, rice, petunia, melon and carnations; and feed safety of 50 plants as of July 2007.

For more information on the Government of Japan's regulatory approach to biotechnology, please refer to the MHLW website (http://www.mhlw.go.jp/english/topics/food/index.html and http://www.mhlw.go.jp/english/topics/qa/gm-food/index.html (Please note that the United States is no longer commercially producing biotech potatoes) and GAIN report JA7037.

Meat and Meat Products

Fresh, prepared, or preserved meat and meat products going into Japan from the United States must be accompanied by U.S. Department of Agriculture, FSIS Form 9290-1 "Certificate to Export to Japan" and FSIS Form 9060-5 (formally MP Form 130) "Meat and Poultry Export Certificate of Wholesomeness." These certificates are issued at the slaughtering or processing facility by a qualified USDA meat and poultry inspector. Export requirements are described on the following FSIS Export Library webpage: http://www.fsis.usda.gov/Regulations & Policies/Japan Requirements/index.asp.

Beef going into Japan is currently operating under the Export Verification Program (EV) due to BSE findings in the United States. Under this program, all beef sent to Japan must be from cattle slaughtered at 20 months of age or below and the meat must be from the facilities audited and approved by the Agricultural Marketing Service (AMS). The official listing of eligible suppliers in the EV Program for Japan and specific requirements are described on the following AMS webpage: http://www.ams.usda.gov/lsg/arc/evjapan.htm

Fruits and Vegetables and Unprocessed Grain Products

A USDA Phytosanitary Certificate PPQ Form 577 must accompany fresh, uncooked, or partially dehydrated fruits and vegetables and unprocessed grain products. Certain fresh fruits and vegetables are currently prohibited under Japan's quarantine law, including apricots, bell peppers, cabbage, chilies, eggplant, peaches, pears, potatoes, radishes, sweet potatoes and yams. For more information contact the Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine, Export Services, 4700 River Road, Unit 140, Riverdale, MD 20737-1228, (301) 734-8537.

Frozen Fruits and Vegetables That Are Permitted Entry

Those frozen fruits and vegetables which are permitted entry by the Japanese government in their fresh form (not heated prior to freezing) may be self-certified by the U.S. processor, exporter or state department of agriculture. Self-certification requires that the following information be placed on the shipper's invoice, which will accompany the product:

- 1. Date of product freezing
- 2. Temperature of freezing (must be at least zero degrees Fahrenheit)
- 3. Name and signature of responsible company official or representative
- 4. Title of company
- 5. Date of signature
- 6. Name of company
- 7. Product description
- 8. Quantity of product being shipped

Frozen Fruits and Vegetables That Are Prohibited Entry

Those frozen fruits and vegetables which are prohibited import to Japan in their fresh (raw) state (except for frozen whole apple) must be certified for export to Japan by the USDA AMS Form FV 146, FV 147 or FV 149 "Certificate of Quality and Condition." For more information, contact AMS, Processed Products Branch, Fruit and Vegetable Program, Room 0709-South Building, Washington, D.C. 20250-0240, telephone (202) 720-4693. Frozen whole apple requires PPQ certification from APHIS (Plant Protection and Quarantine, Export Services, 4700 River Road, Unit 140, Riverdale, MD 20737-1228, (301) 734-8537).

VIII. COPYRIGHT/TRADEMARK LAWS

International trademarks are not protected in Japan. Trademarks must be registered at the Patents, Trademarks and Licensing Office in Japan. The first applicant for a trademark is entitled to its registration.

IX. IMPORT CERTIFICATION AND DOCUMENTATION REQUIREMENTS

Firms interested in importing food, food additives, containers/packages, or any other food related apparatus to Japan must submit a "Notification Form of Food Importation" to the Food Sanitation Inspection Section of the Quarantine Station, Ministry of Health, Labor, and Welfare. The Quarantine Station will examine the product to determine if it conforms to the Japanese Food Sanitation Law. Products that require examination will be inspected on the spot at a designated bonded warehouse. Samples will be taken and forwarded for laboratory analysis.

The product will be allowed entry into Japan once it is examined and found to be in compliance with Japanese food regulations. The Notification Form is stamped if the food requires no examination and is found to be in compliance with the Japanese Food Sanitation Law.

Details of food importing procedures may be viewed at the following MHLW website: (http://www.mhlw.go.jp/english/topics/importedfoods/1.html)

APPENDIX I - CONTACT INFORMATION FOR IMPORT DUTIES AND REQUIREMENTS

The following are names and address of offices you can contact to receive detailed information on regulations and requirements to import into Japan.

Import Duties

The Tokyo Customs Office (TCO) will provide advance ruling on your product's import duties. An official ruling on the tariff category to determine the tariff rate and applicability of imports quotas can be obtained by Japanese importers providing product samples to:

Customs Counselor's Office (ZEIKAN SODANKAN SHITSU) Tokyo, Customs Office 5-5-30, Konan, Minato-ku Tokyo

Tel: 81-3-3472-7001

Labeling Regulations and Health Standards are administered by:

Standards and Evaluation Division Ministry of Health, Labor, and Welfare 1-2-2, Kasumigaseki, Chiyoda-ku Tokyo

Tel: 81-3-3595-2341 Tel: 81-3-3501-4868

Additional Assistance can be obtained by contacting:

Agricultural Affairs Office U.S. Embassy UNIT 45004, Box 226 APO AP 96337-0001

Tel: 81-3-3224-5102 Fax: 81-3-3589-0793

APPENDIX II - OTHER IMPORT SPECIALIST CONTACTS

World Trade Organization (WTO) Inquiry Points

Each member government is responsible for the notification procedures associated with agreements under the WTO. Issues in this report relate to the Sanitary, Phyto-Sanitary (SPS) and Technical Barriers to Trade (TBT) Agreements. WTO obligations include notifying to the WTO any significant trade related proposals that are not substantially the same as international standards, providing copies of the proposed regulation upon request, allowing time for comments, and also providing upon request copies of other relevant documents on existing regulations related to food and agriculture. Information on Japan's regulations, standards and certification procedures can also be obtained through the Inquiry Point listed below:

First International Organization Division Economic Affairs Bureau Ministry of Foreign Affairs 2-2-1 Kasumigaseki, Chiyoda-ku Tokyo

Telephone: 03 (3580) 3311

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